DATA AND SAFETY MONITORING PLAN FOR OAIC-FUNDED STUDIES INVOLVING MORE THAN MINIMAL RISK

## BRIEF STUDY OVERVIEW

Study Title

Principal Investigator

OAIC supporting component (i.e., PESC, RC, REC)

Expected start / end dates

Inclusion/exclusion criteria

Study design and procedures including any intervention(s)

Main outcomes

Analytic plan

## PARTICPANTS’ SAFETY

### Potential Risks and Benefits for Participants

Describe the potential risks and benefits for study participants and society. Include a brief description of specific information collected from individual subjects that will be shared with them; e.g., abnormal test results, genetic information.

### Study Staff Procedures for Collection, Assessment, and Notification of Serious Adverse Events (SAEs), Adverse Events (AEs), Unanticipated Problems (UPs), and Protocol Deviations

Assessment of AEs and SAEs should include classification of severity, expectedness, and relatedness to the study intervention(s). Refer to the [NIA Adverse Event and Serious Adverse EventGuidelines](http://www.nia.nih.gov/sites/default/files/niaaeandsaeguidelinesfinal12_28_07.doc) for more information.

#### Notification

For studies satisfying the [NIH definition of a clinical trial](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html): All deaths and study-related SAEs should be reported to the OAIC Director(s), study principal investigator (PI), Safety Officer/DSMB, IRB, and NIA program official within 48 business hours (excluding weekends and holidays) of the investigators becoming aware of the event, or sooner if required by the institution. The study PI should submit a summary of all other SAEs, AEs, UPs, and protocol deviations, along with any corrective plans to prevent recurrence, to the OAIC Director(s), Safety Officer/DSMB, and NIA program official in routine data and safety reports. (See Frequency below). Reporting to IRB should follow institutional policies.

For studies not considered a clinical trial according to the NIH definition: SAEs, AEs, UPs, and protocol deviations should be reported to the OAIC Director(s), study PI, Safety Officer/DSMB, and IRB according to institutional policies. The NIA program official need not be notified unless upon request.

### Protection Against Study Risks

Describe how adverse events and other risks to participants in the study will be mediated. Specify any events that would preclude a participant from continuing with the study. Also include informed consent procedures and measures to protect participants against risk during the study. See [Informed Consent Template](http://www.nia.nih.gov/sites/default/files/NIAInformedConsentTemplateFINAL.doc) and [Informed Consent Checklist](http://www.nia.nih.gov/sites/default/files/informed_consent_checklist_1_14_08_updated.doc) for more information.

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## PROCEDURES FOR DATA AND SAFETY MONITORING

### Individual(s) Responsible for Reviewing Data and Safety Reports

Reports should be reviewed by either an independent Safety Officer (SO) or a Data and Safety Monitoring Board (DSMB). NIA generally considers monitoring by study staff as an inadequate level of safety monitoring in studies involving more than minimal risk.

The SO or DSMB members should not be directly involved in the conduct of the study nor have scientific, proprietary, financial, or other interests that may affect independent decision-making. The SO or DSMB members need not be external to the institution, except as indicated below.

It is acceptable to establish a standing DSMB composed of members within an institution even though an independent SO would suffice. If studies are proposed that require expertise not already represented on a standing DSMB, NIA may require additional DSMB member(s) for such studies. In unusual cases, if a proposed study is considered high risk, NIA may require a DSMB composed of members entirely outside the institution.

Data and safety reports must also be reviewed by the OAIC Director(s) or a named designee authorized to act on behalf of the OAIC Director(s). In the yearly progress report to NIH, the OAIC Director and/or designee should certify that s/he has read all data and safety reports and that corrective actions have been taken where there were concerns, or that no concerns were noted.

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### Verification of eligibility criteria

Prior to study initiation, the SO/DSMB should verify that each study will have an inclusion/exclusion criteria checklist that is appropriate for the study and that will be used for each subject.

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### Frequency of Data and Safety Monitoring

Reports should be reviewed at a frequency commensurate with risk, generally every 3-6 months. Unscheduled reviews may be conducted if necessary at the request of the OAIC Director, study PI, SO/DSMB, or NIA program official.

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### Content of Data and Safety Monitoring Reports

Reports should include, at a minimum, study status; descriptions of all SAEs, AEs, UPs, and protocol deviations; and any abnormal laboratory, imaging, and other test results. The study PI should attest that to his/her knowledge the list of SAEs, AEs, UPs, and protocol deviations is complete or that no SAEs, AEs, UPs, and protocol deviations occurred. Reminder: Enrollment of a subject who fails to meet eligibility criteria is a protocol deviation.